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EXAMINER	
THANGAVELU, KANDASAMY	
ART UNIT	**PAPER NUMBER**
2123	

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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO 90C (Rev 10/03)

Office Action Summary	Application No.	Applicant(s)	
	10/066,293	ASCENZI ET AL.	
	Examiner	Art Unit	
	Kandasamy Thangavelu	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _31 January 2002_.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-26_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-6,10,11,16-23 and 26_ is/are rejected.

7)☒ Claim(s) _7-9,12-15,24 and 25_ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _31 January 2002_ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-26 of the application have been examined.

Information Disclosure Statement

2. Acknowledgment is made of the information disclosure statements filed on March 6, 2002 and April 15, 2002, together with copies of the papers. The papers have been considered in reviewing the claims.

Drawings

3. The drawings are objected to; see a copy of Form PTO-948 for an explanation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 10 and 20 are rejected under 35 U.S.C. § 102(b) as being anticipated by **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993).

5.1 **Crolet et al.** teaches methods, apparatus and computer program products for automated visual inspection. Specifically, as per claim 1, **Crolet et al.** teaches a model of compact adult bone, wherein the model comprises the viscoelastic properties of at least one type of a secondary osteon (Page 677, Abstract; Page 677, CL2, Para 1 to Para 2; Page 678, CL2, Para 4 to Page 682, CL2, Para 3).

Per claim 2: **Crolet et al.** teaches that the secondary osteon is a longitudinal osteon or an alternate osteon (Page 683, CL1, Para 3 and 4).

Per claim 10: **Crolet et al.** teaches the model comprising the viscoelastic properties of longitudinal and secondary alternate osteons (Page 683, CL1, Para 3 and 4).

Per claim 20: **Crolet et al.** teaches a method of preparing a model of the viscoelastic properties of bone, wherein the method comprises determining viscoelastic properties of alternate and longitudinal osteons (Page 677, Abstract; Page 677, CL2, Para 1 to Para 2; Page 678, CL2, Para 4 to Page 682, CL2, Para 3; Page 683, CL1, Para 3 and 4).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 3, 4, 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Carter et al.** ("Mechanical properties and composition of Cortical Bone", March 1978), and further in view of **Wolfinbarger, Jr. et al.** (U.S. Patent 6,293,970).

8.1 As per claim 3, **Crolet et al.** teaches teach the model of claim 1. **Crolet et al.** teaches that viscoelastic properties comprises at least one parameter selected from the group consisting of collagen content (Page 679, CL2, Para 1; Page 684 CL2, Para 2), hydroxyapatite content (Page 679, CL1, Para 3; Page 679, CL2, Para 1; Page 684 CL2, Para 4), collagen bundle

orientation relative to osteon axis (Page 683, CL1, Para 3 and 4) and content of porosity fluids (Page 677, CL2, Para 2).

Crolet et al. does not expressly teach that the viscoelastic properties comprises at least one parameter selected from the group consisting of mechanical properties. **Carter et al.** teaches that the viscoelastic properties comprises at least one parameter selected from the group consisting of mechanical properties (Page 192, CL2, Para 2; Page 192, CL1, Para 1), because the changes in mechanical properties affect the response of the bone to imposed loads, making the bone more or less resistant to fracture (Page 192, CL2, Para 2). It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the model of **Crolet et al.** with the model of **Carter et al.** that included the viscoelastic properties comprising at least one parameter selected from the group consisting of mechanical properties. The artisan would have been motivated because the changes in mechanical properties would affect the response of the bone to imposed loads, making the bone more or less resistant to fracture.

Crolet et al. does not expressly teach that the viscoelastic properties comprises at least one parameter selected from the group consisting of mucopolysaccharide content. **Wolfinbarger, Jr. et al.** teaches that the viscoelastic properties comprises at least one parameter selected from the group consisting of mucopolysaccharide content (CL1, L30-32), because the bone tissue comprises osteoid and minerals; and the osteoid contains non-sulfated mucopolysaccharides (CL1, L28-32) and as per **Carter et al.** the relationships between stresses and strains at a particular point in the bone are governed by the material properties of the local bone tissues (Page 192, CL1, Para 1). It would have been obvious to one of ordinary skill in the

art at the time of Applicants' invention to modify the model of **Crolet et al.** with the model of **Wolfinbarger, Jr. et al.** that included the viscoelastic properties comprising at least one parameter selected from the group consisting of mucopolysaccharide content. The artisan would have been motivated because the bone tissue comprises osteoid and minerals; and the osteoid contains non-sulfated mucopolysaccharides and the relationships between stresses and strains at a particular point in the bone are governed by the material properties of the local bone tissues.

Crolet et al. does not expressly teach that the viscoelastic properties comprises at least one parameter selected from the group consisting of osteocyte content. **Wolfinbarger, Jr. et al.** teaches that the viscoelastic properties comprises at least one parameter selected from the group consisting of osteocyte content (CL1, L36-40), because the bone tissue is laid down around the osteocytes and these cells are found in small interconnected channels which are interconnected through the Haversian canal system (CL1, L36-40) and the bone tissue is organized into osteons made up of collagen fiber bundles whose orientation affect the mechanical behavior of the osteons (CL1, L40-49). It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the model of **Crolet et al.** with the model of **Wolfinbarger, Jr. et al.** that included the viscoelastic properties comprising at least one parameter selected from the group consisting of osteocyte content. The artisan would have been motivated because the bone tissue is laid down around the osteocytes and these cells are found in small interconnected channels which are interconnected through the Haversian canal system and the bone tissue is organized into osteons made up of collagen fiber bundles whose orientation affect the mechanical behavior of the osteons.

Crolet et al. does not expressly teach that the viscoelastic properties comprises at least one parameter selected from the group consisting of osteoblast content. **Carter et al.** teaches that the viscoelastic properties comprises at least one parameter selected from the group consisting of osteoblast content (Page 194, CL2, Para 2), because osteoblasts surround the bone surface in woven fibred bone; these osteoblasts deposit successive layers of new bone forming the lamellae of secondary Osteons; these microstructural characteristics affect the mechanical properties of the bone tissue (Page 194, CL2, Para 2 to Page 195, CL1, Para 1; Page 192, CL2, Para 2). It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the model of **Crolet et al.** with the model of **Carter et al.** that included the viscoelastic properties comprising at least one parameter selected from the group consisting of osteoblast content. The artisan would have been motivated because osteoblasts surround the bone surface in woven fibred bone; these osteoblasts deposit successive layers of new bone forming the lamellae of secondary Osteons; these microstructural characteristics would affect the mechanical properties of the bone tissue.

8.2 As per claim 4, **Crolet et al., Carter et al.** and **Wolfinbarger, Jr. et al.** teach the model of claim 3. **Crolet et al.** teaches that viscoelastic properties comprises collagen content (Page 679, CL2, Para 1; Page 684 CL2, Para 2), hydroxyapatite content (Page 679, CL1, Para 3; Page 679, CL2, Para 1; Page 684 CL2, Para 4) and collagen bundle orientation relative to osteon axis (Page 683, CL1, Para 3 and 4).

Crolet et al. does not expressly teach that the viscoelastic properties comprises mechanical properties. **Carter et al.** teaches that the viscoelastic properties comprises mechanical properties (Page 192, CL2, Para 2; Page 192, CL1, Para 1), because the changes in mechanical properties affect the response of the bone to imposed loads, making the bone more or less resistant to fracture (Page 192, CL2, Para 2). It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the model of **Crolet et al.** with the model of **Carter et al.** that included the viscoelastic properties comprising mechanical properties. The artisan would have been motivated because the changes in mechanical properties would affect the response of the bone to imposed loads, making the bone more or less resistant to fracture.

Crolet et al. does not expressly teach that the viscoelastic properties comprises mucopolysaccharide content. **Wolfinbarger, Jr. et al.** teaches that the viscoelastic properties comprises mucopolysaccharide content (CL1, L30-32), because the bone tissue comprises osteoid and minerals; and the osteoid contains non-sulfated mucopolysaccharides (CL1, L28-32) and as per **Carter et al.** the relationships between stresses and strains at a particular point in the bone are governed by the material properties of the local bone tissues (Page 192, CL1, Para 1). It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the model of **Crolet et al.** with the model of **Wolfinbarger, Jr. et al.** that included the viscoelastic properties comprising mucopolysaccharide content. The artisan would have been motivated because the bone tissue comprises osteoid and minerals; and the osteoid contains non-sulfated mucopolysaccharides and the relationships between stresses and strains at a particular point in the bone are governed by the material properties of the local bone tissues.

8.3 As per claim 11, **Crolet et al.** teaches the model of claim 10. **Crolet et al.** teaches that viscoelastic properties comprises collagen content (Page 679, CL2, Para 1; Page 684 CL2, Para 2), hydroxyapatite content (Page 679, CL1, Para 3; Page 679, CL2, Para 1; Page 684 CL2, Para 4) and collagen bundle orientation relative to osteon axis (Page 683, CL1, Para 3 and 4).

Crolet et al. does not expressly teach that the viscoelastic properties comprises mechanical properties. **Carter et al.** teaches that the viscoelastic properties comprises mechanical properties (Page 192, CL2, Para 2; Page 192, CL1, Para 1), because the changes in mechanical properties affect the response of the bone to imposed loads, making the bone more or less resistant to fracture (Page 192, CL2, Para 2). It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the model of **Crolet et al.** with the model of **Carter et al.** that included the viscoelastic properties comprising mechanical properties. The artisan would have been motivated because the changes in mechanical properties would affect the response of the bone to imposed loads, making the bone more or less resistant to fracture.

Crolet et al. does not expressly teach that the viscoelastic properties comprises mucopolysaccharide content. **Wolfinbarger, Jr. et al.** teaches that the viscoelastic properties comprises mucopolysaccharide content (CL1, L30-32), because the bone tissue comprises osteoid and minerals; and the osteoid contains non-sulfated mucopolysaccharides (CL1, L28-32) and as per **Carter et al.** the relationships between stresses and strains at a particular point in the bone are governed by the material properties of the local bone tissues (Page 192, CL1, Para 1).

It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the model of **Crolet et al.** with the model of **Wolfinbarger, Jr. et al.** that included the viscoelastic properties comprising mucopolysaccharide content. The artisan would have been motivated because the bone tissue comprises osteoid and minerals; and the osteoid contains non-sulfated mucopolysaccharides and the relationships between stresses and strains at a particular point in the bone are governed by the material properties of the local bone tissues.

8.4 As per Claim 21, it is rejected based on the same reasoning as Claim 11, supra. Claim 21 is a method claim reciting the same limitations as Claim 11, as taught throughout by **Crolet et al., Carter et al.** and **Wolfinbarger, Jr. et al.**

9. Claims 5, 6, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Carter et al.** ("Mechanical properties and composition of Cortical Bone", March 1978), and further in view of **Wolfinbarger, Jr. et al.** (U.S. Patent 6,293,970) and **Ascenzi et al.** ("The torsional properties of single selected osteons", October 1993).

9.1 As per claim 5, **Crolet et al., Carter et al.** and **Wolfinbarger, Jr. et al.** teach the model of claim 3. **Crolet et al.** teaches that osteon mechanical properties comprises hydroxyapatite content (Page 679, CL1, Para 3; Page 679, CL2, Para 1; Page 684 CL2, Para 4).

Crolet et al. does not expressly teach that osteon mechanical properties comprises an angle-of-twist as a function of torque. **Ascenzi et al.** (October 1993) teaches that osteon mechanical properties comprises an angle-of-twist as a function of torque (Abstract; Page 875, CL2, Para 3; Page 880, Fig. 4), as the longitudinal osteons indicate most resistance to torsional loading; and the transverse osteons have low resistance to torsional loading (Abstract, L8-10). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (October 1993) that included osteon mechanical properties comprising an angle-of-twist as a function of torque. The artisan would have been motivated because the longitudinal osteons would indicate most resistance to torsional loading; and the transverse osteons would have low resistance to torsional loading.

Crolet et al. does not expressly teach that osteon mechanical properties comprises an angle-of-twist as a function of strain rate or time. **Ascenzi et al.** (October 1993) teaches that osteon mechanical properties comprises an angle-of-twist as a function of strain rate or time (Page 879, CL1, Para 5 to Page 879, CL2, Para 1), as the osteon failure depends on the strain rate and time (Page 879, CL1, Para 5 to Page 879, CL2, Para 1). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (October 1993) that included osteon mechanical properties comprising an angle-of-twist as a function of strain rate or time. The artisan would have been motivated because the osteon failure would depend on the strain rate and time.

9.2 As per claim 6, **Crolet et al., Carter et al., Wolfinbarger, Jr. et al.** and **Ascenzi et al.** (October 1993) teach the model of claim 5.

Crolet et al. does not expressly teach that the angle-of-twist as a function of torque is derived from tests conducted under monotonic or dynamic loading. **Ascenzi et al.** (October 1993) teaches that the angle-of-twist as a function of torque is derived from tests conducted under monotonic or dynamic loading (Page 879, CL1, Para 5 to Page 879, CL2, Para 1; Page 880, CL1, Para 4 to Page 881, CL2, Para 1; Page 880, Fig. 4), as the stress and strain produced during application of the progressive loading allows determination of the unchecked twisting of the specimen indicating osteon failure (Page 879, CL1, Para 5 to Page 879, CL2, Para 1). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (October 1993) that included the angle-of-twist as a function of torque being derived from tests conducted under monotonic or dynamic loading. The artisan would have been motivated because the stress and strain produced during application of the progressive loading would allow determination of the unchecked twisting of the specimen indicating osteon failure.

9.3 As per claim 22, **Crolet et al., Carter et al.** and **Wolfinbarger, Jr. et al.** teach the method of claim 21. **Crolet et al.** teaches that the mechanical properties are determined by evaluating hydroxyapatite content (Page 679, CL1, Para 3; Page 679, CL2, Para 1; Page 684 CL2, Para 4).

Crolet et al. does not expressly teach that the mechanical properties are determined by evaluating angle-of-twist as a function of torque, strain rate, or time. **Ascenzi et al.** (October

1993) teaches that the mechanical properties are determined by evaluating angle-of-twist as a function of torque (Abstract; Page 875, CL2, Para 3; Page 880, Fig. 4), as the longitudinal osteons indicate most resistance to torsional loading; and the transverse osteons have low resistance to torsional loading (Abstract, L8-10). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Ascenzi et al.** (October 1993) that included the mechanical properties being determined by evaluating angle-of-twist as a function of torque. The artisan would have been motivated because the longitudinal osteons would indicate most resistance to torsional loading; and the transverse osteons would have low resistance to torsional loading.

Crolet et al. does not expressly teach that the mechanical properties are determined by evaluating an angle-of-twist as a function of strain rate or time. **Ascenzi et al.** (October 1993) teaches that the mechanical properties are determined by evaluating an angle-of-twist as a function of strain rate or time (Page 879, CL1, Para 5 to Page 879, CL2, Para 1), as the osteon failure depends on the strain rate and time (Page 879, CL1, Para 5 to Page 879, CL2, Para 1). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Ascenzi et al.** (October 1993) that included the mechanical properties being determined by evaluating an angle-of-twist as a function of strain rate or time. The artisan would have been motivated because the osteon failure would depend on the strain rate and time.

9.4 As per claim 23, **Crolet et al., Carter et al., Wolfinbarger, Jr. et al.** and **Ascenzi et al.** (October 1993) teach the method of claim 22.

Crolet et al. does not expressly teach that angle-of-twist as a function of torque is determined by quasi-static torsional loading to rupture. **Ascenzi et al.** (October 1993) teaches that angle-of-twist as a function of torque is determined by quasi-static torsional loading to rupture (Page 879, CL1, Para 5 to Page 879, CL2, Para 1; Page 880, CL1, Para 4 to Page 881, CL2, Para 1; Page 880, Fig. 4), as the stress and strain produced during application of the progressive loading allows determination of the unchecked twisting of the specimen indicating osteon failure (Page 879, CL1, Para 5 to Page 879, CL2, Para 1). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Ascenzi et al.** (October 1993) that included the angle-of-twist as a function of torque being determined by quasi-static torsional loading to rupture. The artisan would have been motivated because the stress and strain produced during application of the progressive loading would allow determination of the unchecked twisting of the specimen indicating osteon failure.

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Ascenzi et al.** ("The torsional properties of single selected osteons", October 1993).

10.1 As per claim 16, **Crolet et al.** teaches the model of claim 1. **Crolet et al.** does not expressly teach the model comprising a Finite Element Model (FEM). **Ascenzi et al.** (October

1993) teaches the model comprising a Finite Element Model (FEM) (Page 880, CL1, Para 1), as the mechanical properties of the osteons can be determined by applying finite element analysis (Abstract, L8-10). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the model of **Crolet et al.** with the model of **Ascenzi et al.** (October 1993) that included the model comprising a Finite Element Model (FEM). The artisan would have been motivated because the mechanical properties of the osteons could be determined by applying finite element analysis.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Carter et al.** ("Mechanical properties and composition of Cortical Bone", March 1978).

11.1 As per claim 17, **Crolet et al.** teaches the model comprising the viscoelastic properties of secondary longitudinal and alternate osteons (Page 683, CL1, Para 3 and 4).

Crolet et al. does not expressly teach a method of predicting deformation and fractures of compact adult bone comprising using a model of compact adult bone. **Carter et al.** teaches a method of predicting deformation and fractures of compact adult bone comprising using a model of compact adult bone (Page 192, CL1, Para 1; Page 192, CL2, Para 1; Page 198, CL1, Para 2; Page 199, CL2, Para 2 to Page 200, CL1, Para 1), because sustained loading of the cortical bone produces a gradual increase in deformation with time; the rapidity of the deformation or the

strain rate depends on the stress-strain behavior of the cortical bone (Page 198, CL1, Para 2); and if the stress magnitude during repeated loading are high enough, fatigue failure may result (Page 200, CL1, Para 1). It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the method of **Crolet et al.** with the method of **Carter et al.** that included a method of predicting deformation and fractures of compact adult bone comprising using a model of compact adult bone. The artisan would have been motivated because sustained loading of the cortical bone would produce a gradual increase in deformation with time; the rapidity of the deformation or the strain rate would depend on the stress-strain behavior of the cortical bone; and if the stress magnitude during repeated loading were high enough, fatigue failure might result.

12. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Carter et al.** ("Mechanical properties and composition of Cortical Bone", March 1978), and further in view of **Ascenzi et al.** ("The torsional properties of single selected osteons", October 1993).

12.1 As per claim 18, **Crolet et al.,** and **Carter et al.** teach the method of claim 17. **Crolet et al.** does not expressly teach that the model simulates fracture propagation by calculating stress distribution as a function of a torque applied to the bone. **Ascenzi et al.** (October 1993) teaches that the model simulates fracture propagation by calculating stress distribution as a function of a torque applied to the bone (Page 879, CL1, Para 5 to Page 879, CL2, Para 1; Page 880, CL1,

Para 4 to Page 881, CL2, Para 1; Page 880, Fig. 4), as the longitudinal osteons indicate most resistance to torsional loading; and the transverse osteons have low resistance to torsional loading (Abstract); fractures produced by torsion differ substantially according to the type of osteon (Page 881, CL1, Para 5 to Page 881, CL2, Para 1). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Ascenzi et al.** (October 1993) that included the model simulating fracture propagation by calculating stress distribution as a function of a torque applied to the bone. The artisan would have been motivated because the longitudinal osteons would indicate most resistance to torsional loading; and the transverse osteons would have low resistance to torsional loading; and fractures produced by torsion differ substantially according to the type of osteon.

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Copland III et al.** (U.S. Patent 6,333,313), and further in view of **Agrawal et al.** (U.S. Patent 5,947,893).

13.1 As per claim 19, **Crolet et al.** teaches the model of claim 1. **Crolet et al.** does not expressly teach a method of identifying the requirements of bone reconstruction. **Copland III et al.** teaches a method of identifying the requirements of bone reconstruction (CL8, L9-13), as bone reconstruction requires ability to reconstruct defects in bone tissue resulting from various causes (CL8, L10-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Copland III**

et al. that included a method of identifying the requirements of bone reconstruction. The artisan would have been motivated because bone reconstruction requires ability to reconstruct defects in bone tissue resulting from various causes.

Crolet et al. does not expressly teach a method of identifying the requirements of prosthesis. **Agrawal et al.** teaches a method of identifying the requirements of prosthesis (Abstract, L1-16), as long term stability of the prosthesis requires bone to form an interlock by growing into the prosthesis at the mating surface (CL1, L43-46). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Agrawal et al.** that included a method of identifying the requirements of prosthesis. The artisan would have been motivated because long term stability of the prosthesis would require bone to form an interlock by growing into the prosthesis at the mating surface.

14. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Crolet et al.** ("Compact Bone: Numerical simulation of mechanical characteristics", J. Biomechanics, Vol. 26, No. 6, 1993) in view of **Carter et al.** ("Mechanical properties and composition of Cortical Bone", March 1978) and **Wolfinbarger, Jr. et al.** (U.S. Patent 6,293,970), and further in view of **Hamamoto et al.** (U.S. Patent 5,732,469) and **Ascenzi et al.** ("X-Ray diffraction on cyclically loaded osteons", August 1997).

14.1 As per claim 26, **Crolet et al., Carter et al.** and **Wolfinbarger, Jr. et al.** teach the method of claim 21. **Crolet et al.** does not expressly teach that the collagen-bundle direction

related to osteon axis is determined by circularly polarizing light microscopy, confocal microscopy or X-ray diffraction. **Hamamoto et al.** teaches that the collagen-bundle direction related to osteon axis is determined by circularly polarizing light microscopy or confocal microscopy (CL9, L44-46; CL19, L34-37), as the degree of penetration of the osteoblast can be examined by light microscopy (CL19, L34-37). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Hamamoto et al.** that included the collagen-bundle direction related to osteon axis being determined by circularly polarizing light microscopy or confocal microscopy. The artisan would have been motivated because the degree of penetration of the osteoblast could be examined by light microscopy.

Crolet et al. does not expressly teach that the collagen-bundle direction related to osteon axis is determined by X-ray diffraction. **Ascenzi et al.** (August 1997) teaches that the collagen-bundle direction related to osteon axis is determined by X-ray diffraction (Abstract), as the structural distortions induced by the cyclic loading can be investigated by X-ray diffraction (Abstract, L12-14). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **Crolet et al.** with the method of **Ascenzi et al.** (August 1997) that included the collagen-bundle direction related to osteon axis being determined by X-ray diffraction. The artisan would have been motivated because the structural distortions induced by the cyclic loading can be investigated by X-ray diffraction.

Allowable Subject Matter

15. Claims 7-9, 12-15 and 24-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 703-305-0043. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Teska, can be reached on (703) 305-9704. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-9600.

K. Thangavelu
Art Unit 2123
July 9, 2004

KEVIN J. TESKA
SUPERVISORY
PATENT EXAMINER